

JUL 25 2003



K031182

510(k) Notification: Mortara ELI 200+ Audicor

510(k): ELI 200+ Audicor Device Summary

Submitter:

Date: February 5, 2003

Harlan Van Matre, Manager of Quality Assurance / Regulatory Affairs
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224

Fax: (414) 354-4760
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Contact: Harlan Van Matre (see above)

Trade Name: ELI 200+ Audicor
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S. E. is claimed

The Mortara Instrument's ELI 200+ Audicor Electrocardiograph is a current technology evolution of the Mortara ELI 200 and is substantially equivalent to these legally marketed predicate devices:

- ELI 200 by Mortara Instrument (K920626)
- Inovise's Cardioise Interpretive Software (K001349)
- HP's 1514A ECG/Phono System

The proposed ELI 200+ Audicor is a direct evolution of this Mortara predicate device. It will combine ELI 200 technologies with current technologies including Audicor Correlated Audioelectric Cardiology (COR) technology, resulting in the Mortara ELI 200+ Audicor.

Description:

The ELI 200+ Audicor is an interpretive electrocardiograph that provides simultaneous 12-lead acquisition and is designed to be portable. It also employs Audicor Correlated Audioelectric Cardiology (COR) technology from Inovise Medical, Inc. that will enable acquisition of both 12-lead ECG and heart sound data at the same time. This will be accomplished with a Mortara ELI 200+ electrocardiograph and the use of an Audicor Adaptor and Audicor Sensor. In use, the Audicor Sensor will replace the standard V4 electrode and connect to the Audicor Adaptor, enabling simultaneous acquisition of the ECG signal and an acoustical signal.

The Audicor sensor is a single-use, non-invasive, disposable medical device that has the ability to acquire a single-lead ECG (electrical) signal and a single-lead acoustic signal simultaneously from the skin surface of a patient. It is designed to transfer these signals to an attached Audicor Adaptor, which itself connects and transfers the signals through patient leads to compatible cardiographs such as the Mortara ELI 200+ electrocardiograph for acquisition and analysis.

Intended use:

The ELI 200+ Audicor Option Electrocardiograph is intended to acquire, record and then store acquired cardiac data of symptomatic patients. The ELI 200+ Audicor Option can also be used to acquire both 12-lead ECG and heart sound data at the same time. The cardiac data is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with LVH, acute and age undetermined MI and detection of S3/S4 heart sounds. The S3/S4 heart sound is useful in the identification of cardiac conditions associated with Left Ventricular dysfunction.



510(k) Notification: Mortara ELI 200+ Audicor

Indications for use:

- The device is indicated for use to acquire, analyze, display and print ECG and heart sound (COR) data.
- The device is indicated for use to provide interpretation of the data for consideration by physicians.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG and heart sound data (COR) offered by the device are only significant when used in conjunction with physician overread as well as consideration of all other relevant patient data.
- The device is indicated for use on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.
- Evaluation of cardiac conditions such as LVH, Acute and Age Undetermined MI and detection of S3 and S4 heart sounds.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Mortara Instrument, Inc.
c/o Ms. Chantel Carson
Group Ldr Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062-2096

Re: K031182

Trade Name: ELI 200+ Audicor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 8, 2003
Received: Jul 9, 2003

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

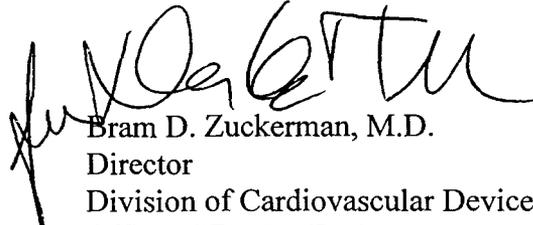
Page 2 – Ms. Chantel Carson

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K031182

Device Name: ELI 200+ AUDICOR

The ELI 200+ with Audicor is a resting electrocardiograph that provides simultaneous 12-lead ECG acquisition and heart sound data (COR – Correlated Audioelectric Cardiography).

The ELI 200+ Audicor Option Electrocardiograph is intended to acquire, record and then store acquired cardiac data of symptomatic patients. The ELI 200+ Audicor Option can also be used to acquire both 12-lead ECG and heart sound data at the same time. The cardiac data is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with LVH, Acute and Age Undetermined MI and detection of S3/S4 Heart Sounds. The S3 and S4 Heart Sounds are useful in the identification of cardiac conditions associated with Left Ventricular dysfunction.

This device is appropriate for the indications listed below:

- The device is indicated for use to acquire, analyze, display and print ECG and heart sound (COR) data.
- The device is indicated for use to provide interpretation of the data for consideration by physicians.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG and heart sound data (COR) offered by the device are only significant when used in conjunction with physician overread as well as consideration of all other relevant patient data.
- The device is indicated for use on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.
- Evaluation of cardiac conditions such as LVH, Acute and Age Undetermined MI and detection of S3 and S4 heart sounds.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)


 Concurrence of SDRH, Office of Device Evaluation (ODE)
 (Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K031182

Prescription Use
(Per 21CFR801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)